

REMARKS

Applicant respectfully requests reconsideration. Claims 18-36, 51-59 and 64-69 were previously pending in this application. Claims 18, 19, 22, 31-36, 51-55, 57-59, 64-66 and 69 have been amended to remove the recitation of immunoglobulins and to focus the recitation of the claims on fragments of immunoglobulins, which were part of the claims as previously presented. No new matter has been added.

Sequences in the Specification

The Examiner reminded Applicant of a sequence on page 16 that required a sequence identifier. Applicant has amended the specification to add the appropriate sequence identifier. Applicant also has filed herewith a revised Sequence Listing that includes the sequence of the primer on page 16.

Rejections Under 35 U.S.C. §102

1. The Examiner rejected claims 18-22, 25-27, 31-33, 35 and 51-53 under 35 U.S.C. §102(b) as being anticipated by Ungar-Waron et al. (Isr. J. Vet. Med. 1987, Vol. 43(3), pages 198-203) as evidenced by Hamers-Casterman et al. (Nature 3 June 1993, Vol. 363, pages 446-448), Roux et al. (PNAS USA 1998, Vol. 95, pages 11804-11089), WO 94/25591, van der Linden et al. (Biochimica et Biophysica Acta 1999, 1431: 37-46), and EP 0739981 A1. Applicant respectfully requests reconsideration based on the amendments of the claims.

Applicant does not concede that the instant claims are anticipated by Ungar-Waron et al., does not admit that the proteins shown in Ungar-Waron are Camelid IgG heavy chains that lack light chains, and reserves the right to pursue claims that include the scope of the instant claims prior to this amendment. However, to facilitate allowance of claims in this application, Applicant has amended the claims to recite only fragments of immunoglobulins that consist

essentially of variable regions of heavy polypeptide chains, or binding parts thereof. The variable regions are devoid of normal light chain interaction sites.

Ungar-Waron does not teach explicitly or inherently such fragments. The Examiner on page 6 of the Office Action has stated that claims reciting fragments are included in the rejection because the 40kDa band of Ungar-Waron “is a fragment of a divalent immunoglobulin that binds antigen”. This is incorrect for at least two reasons. First, there is no evidence that the “40 Kd” protein of Ungar-Waron is an immunoglobulin of the type claimed in this application. Second, even if the Examiner’s assertion that WO 94/25591 teaches the equivalence of camel heavy chain immunoglobulins and Ungar-Waron’s 40kDa protein is accepted for the sake of argument (which Applicant does not concede), there is nothing in WO 94/25591 that teaches that Ungar-Waron provides fragments of immunoglobulins that are devoid of normal light chain interaction sites, as are now claimed. Moreover, the Examiner cannot plausibly argue that Ungar-Waron’s 40kDa protein contains both fragments and whole camel heavy chain immunoglobulins, since that is a physical impossibility.

Accordingly, withdrawal of the rejection of the claims under 35 U.S.C. §102 as anticipated by Ungar-Waron is respectfully requested.

2. The Examiner rejected claims 18-22, 25-27, 31-33, 35 and 51-53 under 35 U.S.C. §102(b) as being anticipated by Grover et al. (Ind. J. Biochem. Biophys. 1983, 20(4): 238-240, as evidenced by WO 94/25591, Satija et al. (Inf. Immun. 1979, 24(2): 567-570), van der Linden et al. (Biochimica et Biophysica Acta 1999, 1431: 37-46), and EP 0739981 A1. Applicant respectfully requests reconsideration.

According to the Examiner, Grover et al. describes “camel IgG2 isotype polyclonal antibodies” seen on a polyacrylamide gel electrophoresis of camel serum. The “camel IgG2” seen by Grover et al., however, are not the same immunoglobulins as claimed by Applicant in the present application. The “camel IgG2 antibodies” seen by Grover et al. are conventional, four-chain immunoglobulins with light chains. In contrast, Applicant claims polypeptides

consisting essentially of a variable domain of a Camelid immunoglobulin that include heavy chain polypeptides devoid of light chains, not conventional four-chain immunoglobulins with light chains as described by Grover et al.

The teaching of Grover et al. is provided in the paragraph bridging pages 238-239, which states that three major classes of immunoglobulins were identified in camel serum and that they were “designated as IgM, IgA, IgG1 and IgG2 based on their shape, position and electrophoretic mobility to cathode as proposed by Butler et al. for various ruminants based on immunoelectrophoresis.” (Emphasis added)

First, this statement clearly indicates that Grover et al. compare the immunoglobulins seen on their polyacrylamide gel with immunoglobulins seen in other ruminants and that they conclude that the immunoglobulins seen on their polyacrylamide gel have the same shape and electrophoretic mobility as the immunoglobulins seen in other ruminants. Other ruminants, however, have only conventional, four-chain immunoglobulins. Accordingly, the immunoglobulins observed by Grover et al. also were conventional, four-chain immunoglobulins with light chains.

Second, the reference of Butler et al. (to which Grover et al. refers) describe the different bovine immunoglobulins (including IgG1 and IgG2) and their characteristics. A copy of Butler et al. has been made of record previously. On Table 1, page 1316, for example, Butler et al. show that IgG1 and IgG2 have a molecular weight of 150 or 163 and that the H-chain of IgG1 and IgG2 has a molecular weight of 54 or 55-58. These molecular weights clearly correspond respectively to the molecular weights of conventional, four-chain immunoglobulins with light chains and to H-chains derived from conventional, four-chain immunoglobulins.

From the above, it can therefore be concluded that the IgG2 seen in Grover et al. are conventional, four-chain immunoglobulins that have light chains. Accordingly, they cannot be the same compounds as the IgG2 described by Applicant in the present invention, which have different molecular weight, which have only two heavy chains and which do not have light chains.

Finally, the claims as amended recite only fragments of immunoglobulins that consist essentially of variable regions of heavy polypeptide chains, or binding parts thereof. The variable regions are devoid of normal light chain interaction sites.

Accordingly, withdrawal of the rejection of the claims under 35 U.S.C. §102 as anticipated by Grover is respectfully requested.

Double Patenting Rejection

1. The Examiner provisionally rejected claims 18-22, 25-27, 31, 32 and 51-54 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-27 of copending Application No. 11/350,900 as evidenced by van der Linden et al. (Biochimica et Biophysica Acta 1999, 1431: 37-46).

While not conceding that the instant claims are obvious over the cited claims of US 11/350,900, Applicant respectfully notes that the claims of US 11/350,900 are not yet allowed and therefore this rejection should be withdrawn if the instant claims are otherwise allowable.

Accordingly, withdrawal of the rejection of claims 18-22, 25-27, 31, 32 and 51-54 is respectfully requested.

2. The Examiner provisionally rejected claims 33 and 35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-27 of copending Application No. 11/350,900 in view of Harlow and Lane.

While not conceding that the instant claims are obvious over the cited claims of US 11/350,900, Applicant respectfully notes that the claims of US 11/350,900 are not yet allowed and therefore this rejection should be withdrawn if the instant claims are otherwise allowable.

Accordingly, withdrawal of the rejection of claims 33 and 35 is respectfully requested.

3. The Examiner rejected claims 18-22, 25-27, 31, 32 and 51-54 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,005,079 as evidenced by WO 94/25591, by an admission in the instant specification on page 13 at paragraphs 2-5, and as evidenced by van der Linden (*Biochimica et Biophysica Acta* 1999, 1431: 37-46).

Applicant respectfully disagrees that claims 18-22, 25-27, 31, 32 and 51-54 are obvious over the cited claims of US 6,005,079. However, to facilitate allowance of the instant claims, Applicant submits herewith a Terminal Disclaimer to obviate the rejection based on commonly owned U.S. Patent No. 6,005,079.

Accordingly, withdrawal of the rejection of claims 18-22, 25-27, 31, 32 and 51-54 is respectfully requested.

4. The Examiner rejected claims 33 and 35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,005,079 in view of Harlow and Lane.

Applicant respectfully disagrees that claims 33 and 35 are obvious over the cited claims of US 6,005,079. However, to facilitate allowance of the instant claims, Applicant submits herewith a Terminal Disclaimer to obviate the rejection based on commonly owned U.S. Patent No. 6,005,079.

Accordingly, withdrawal of the rejection of claims 33 and 35 is respectfully requested.

5. The Examiner rejected claims 18-22, 25-27, 31-33, 35 and 51-54 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,840,526 as evidenced by an admission in the instant specification on page 13 at paragraphs 2-5 and by van der Linden (*Biochimica et Biophysica Acta* 1999, 1431: 37-46) and WO 94/25591.

Applicant respectfully disagrees that claims 18-22, 25-27, 31-33, 35 and 51-54 are obvious over the cited claims of US 5,840,526. However, to facilitate allowance of the instant claims, Applicant submits herewith a Terminal Disclaimer to obviate the rejection based on commonly owned U.S. Patent No. 5,840,526.

Accordingly, withdrawal of the rejection of claims 18-22, 25-27, 31-33, 35 and 51-54 is respectfully requested.

6. The Examiner rejected claims 18-22, 25-27, 31-33, 35 and 51-54 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,765,087 as evidenced by van der Linden et al. (*Biochimica et Biophysica Acta* 1999, 1431: 37-46).

Applicant respectfully disagrees that claims 18-22, 25-27, 31-33, 35 and 51-54 are obvious over the cited claims of US 6,765,087. However, to facilitate allowance of the instant claims, Applicant submits herewith a Terminal Disclaimer to obviate the rejection based on commonly owned U.S. Patent No. 6,765,087.

Accordingly, withdrawal of the rejection of claims 18-22, 25-27, 31-33, 35 and 51-54 is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
Cecile Casterman et al., Applicant(s)

By: /John R. Van Amsterdam/
John R. Van Amsterdam
Reg. No. 40,212
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

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